ESTIMATION OF EXPOSURE OF PERSONS IN CALIFORNIA TO PESTICIDE PRODUCTS THAT CONTAIN AMITRAZ

By

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EXECUTIVE SUMMARY

Amitraz is the common name for N'-methyl-N'-2,4-xylyl-N(N-2,4-xylylformimidoyl) formamidine, a miticide and insecticide registered for use on cotton, livestock, pears and in pet collars. EPA has classified amitraz as a quantifiable Group C/D carcinogen for which no clear evidence of oncogenic potential has been demonstrated. Studies submitted in response to the Birth Defects Prevention Act (SB 950) indicate that exposure to amitraz may cause adverse health effects (tumors and reproductive toxicity). A dermal absorption study in rats observed that with a 10 hour exposure, 13.8% of a 10 μg/cm^2 dose was eventually absorbed and excreted in 120 hours with minute amounts remaining in the carcass and gastrointestinal tract. Orally administered amitraz in rats is rapidly hydrolyzed in the stomach and eventually excreted in the urine as 4-acetamido-3-methyl benzoic acid (FBC-31158), 4-formamido-3-methyl benzoic acid (BTS-39098) and the highly polar conjugates of FBC-31158, BTS-39098, N-(2,4-dimethylphenol)-N-methyl formamidine (BTS-27271) and 4-amino-3-methylbenzoic acid (BTS-28369). A biomonitoring study for operators mixing, loading and applying amitraz in a pear orchard observed the excretion of amitraz metabolites in urine averaged 0.51 mg during the 120 hour collection period. Workers involved in the aerial application of amitraz to cotton may incur 3.51-11.4 mg of dermal exposure per day during mixing/loading, application or flagging. The maximum dermal exposure to workers making treatments to livestock was estimated to be 2.42 mg/day for a large cow-calf ranch. Harvesters picking in an pear orchard treated 7 days previously with amitraz could experience 20.3 mg of dermal exposure per 8-hour workday. The estimated absorbed daily dose for a veterinarian placing amitraz collars on dogs was 0.05 μg/kg.

California Environmental Protection Agency
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Human Exposure Assessment

AMITRAZ

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GENERAL PHYSICAL AND CHEMICAL PROPERTIES

Amitraz is the common name for N-methyl-N'-2,4-xylyl-N(N-2,4- xylylformimidoyl) formamidine, a miticide and insecticide sold under the trade names "Mitac®" and "Taktic®" by the Nor-Am Company (Upjohn Company, 1976). It is a pale, straw colored crystalline solid with a melting point of 86-87^{o}C. Amitraz has a specific gravity of 0.905 at 20^{o}C and a boiling point of 140^{o}C. The vapor pressure of amitraz has been determined by an effusion method to be 3.8 X 10^{-7} mm mercury at 20^{o}C. Amitraz is poorly soluble in water (less than 1 ppm at 22^{o}C), but is readily soluble in most organic solvents (1 gm dissolving in 1.5 ml of xylene). This compound is relatively stable to heating in the dry form or when immersed in an organic solvent but becomes increasingly unstable in water as the pH drops. In an aqueous solution with a pH of 6.18, the half-life is 172 minutes at room temperature. However, when the pH is lowered to 4.13, the half-life is only 15.3 minutes.

The technical material has a minimal purity of 93% with 2.5% paraformaldehyde added to prevent oxidation (Upjohn Company, 1976). During formulation most of the paraformaldehyde is removed because of its low solubility in the formulating solvents. Only 0.02-0.07% of the formulated product is paraformaldehyde. The primary impurities in the technical material are N,N'- di-(2,4-dimethylphenyl) formansidine (6% or less) and 2,4-xylidine (0.3% or less).

EPA STATUS

The manufacturer of amitraz applied for a registration on apples and pears in 1976. In April 1977, before registration could be completed, the Environmental Protection Agency (EPA) issued a Rebuttable Presumption Against Registration (RPAR) document for amitraz (U.S. EPA, 1979). Based on an 80-week mouse oncogenicity study, the Agency concluded there is "weakly positive evidence" that amitraz is a possible human carcinogen.

In October 1979, the RPAR was concluded with the recommendation that a four-year conditional registration was justified on pears, but not on apples. Amitraz became a federally restricted material with a 24-hour reentry interval and a seven-day pre-harvest interval. Labeling was

amended to require protective clothing to be worn by the mixer/loader and applicator. The Agency determined that the continued registration of amitraz on pears would not pose any unreasonable risks and granted a four year conditional registration in January 1980.

In October 1987, the guidance document for the reregistration of amitraz was issued (U.S. EPA, 1987a). The EPA's Cancer Assessment Group (CAG) has completed their evaluation of the new mouse oncogenicity study. The initial CAG review, based on the weight of evidence, indicated that amitraz should be considered as a possible human carcinogen in the lower portion of the group "C" range. Their conclusions were reviewed by the FIFRA Scientific Advisory Panel (SAP) along with additional opinions from the manufacturer of amitraz. The SAP concluded that amitraz should be classified in group D (not classifiable as to human carcinogenicity). EPA has since reassessed its own position in light of the industry presentation and the SAP opinion. The Agency has now concluded that amitraz is a group C/D carcinogen in regard to it's oncogenic potential. As a result, amitraz will no longer be required by the EPA to be registered as a restricted use pesticide.

In the guidance document, the Agency also listed the conditions necessary to reregister manufacturing-use and end-use products. The makers of manufacturing-use products must conduct additional environmental fate, avian reproduction and metabolism studies to maintain registration.

USAGE

The annual Pesticide Use Reports compiled by the Department of Pesticide Regulation (DPR) indicate that 5,834 lbs. of active ingredient (a.i.) were used to treat 4,126 acres of pears in 1991 (DPR, 1993). In 1992, 8,952 lbs. of a.i. were used to treat 6, 327 acres of pears (DPR, 1994). Although amitraz is now registered for use on cotton under the trade name Ovasyn®, the use report from the 1993 season indicates only 16 lbs. of a.i. was applied (DPR, 1995). Since livestock are not considered an agricultural commodity in California for the purposes of reporting pesticide use, dairymen, ranchers and feedlot operators are not required to report use to the Agricultural Commissioner. As a consequence, data regarding the annual amount of amitraz applied to livestock is not available.

FORMULATIONS

The Nor-Am Company has registered two formulations of amitraz for use on pears (Mitac® WP and Mitac® EC), a third formulation for use on cotton (Ovasyn®) and a fourth formulation for use on livestock (Taktic®). Mitac® WP (wettable powder) is composed of 50% active ingredient formulated with earth-derived carriers, a surfactant and a dispersing agent. The label allows a maximum application rate of three lbs. of product per acre with a maximum seasonal use of three lbs. of a.i. The pre-harvest interval is seven days. Mitac® EC and Ovasyn® are emulsifiable concentrates formulated with 1.5 lbs. of active ingredient per gallon. A petroleum distillate

blended with an emulsifier make up the remaining percentage (80%) of inerts. Mitac® EC permits 2-4 quarts of product per acre on pears to be applied with a seven-day pre-harvest interval. The maximum seasonal use is three lbs. of a.i. per acre. Ovasyn® permits a label rate of 0.125-0.94 lb. a.i. per acre per application on cotton with a maximum seasonal use of 1.0 lb. a.i. per acre. Taktic® is registered as a miticide/insecticide to control ticks, mange mites and lice on livestock. Taktic® is formulated as a 12.5% (by weight) emulsifiable concentrate with 0.94 lb. of amitraz per gallon. Applications to beef and dairy cattle are made as a mixture of one-two cans (25.7 oz. each) per hundred gallons of water (0.4-0.8% solution by weight). Each animal can be treated with a maximum of two gallons of spray mixture. Swine and their pens are treated with a mixture of one can of product per 50 gallons of water (0.8% solution by weight) to control body lice. The adult pigs are treated with a coarse spray until run off while piglets or weaners can be dipped in the mixture. One manufacturer of pest control products for dogs has registered a pet collar for dogs impregnated with amitraz to control ticks.

LABEL PRECAUTIONS

The protective clothing required for handling products that contain amitraz vary according to the toxicity of the formulation. The pet collar label recommends the handler to wash thoroughly with soap and water after handling the collar. Taktic®, a category III pesticide, requires persons handling it to wear long pants, long-sleeved shirt, chemical resistant gloves, a hat, socks, boots and protective eyewear. Workers mixing and loading Taktic® must also wear a chemical resistant apron. Mitac® EC and WP are category II pesticides that require coveralls to be worn over long-sleeved shirt and long pants, waterproof or chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear, and protective eyewear. In addition workers mixing/loading or cleaning application equipment must wear a chemical resistant apron. The Ovasyn® label requires the same protective clothing to be worn as listed on the Mitac® EC and WP labels. In addition, as a category I liquid pesticide, California regulations require Ovasyn® to be mixed and loaded with a closed system when handled by employees. Under the federal “Worker Protection Standards”, when a "closed system" is used to mix and load a pesticide with the signal word DANGER or WARNING, workers can wear long-sleeved shirt and long pants, shoes and socks, chemical resistant gloves, chemical resistant apron and protective eyewear (if the closed system is pressurized). This protective clothing regime is consistent with the California regulations for protective clothing when a "closed system " is used. The label prohibits entry into treated areas for 24 hours after the application unless the appropriate protective clothing is worn. Workers entering treated areas after the 24-hour period has elapsed can wear normal work clothing. The Ovasyn® label and the labels for Mitac® EC and WP caution the handler that repeated skin contact may cause an allergic reaction.

WORKER ILLNESSES

The DPR, Worker Health and Safety Branch (WH&S) has not received any reports of worker illnesses due to exposure to amitraz from 1984-1993, the last year for which published reports

are available (CDFA, 1985; CDFA, 1986; CDFA, 1987; Edmiston and Richmond, 1988; Mehler *et al.*, 1990; Mehler, 1991; DPR, 1993a; DPR, 1994a; DPR, 1994b; DPR, 1995a).

DERMAL TOXICITY

The effects of dermal exposure to amitraz have been well studied. Dermal irritation studies were conducted on rabbits with the formulated EC and WP products applied as a single dose (up to 2000 mg/kg) or as multiple doses (500 ppm) (BFC Chemicals, 1981). Systemic effects of hypothermia, hyperglycemia and depression were reported but subsided after 48 hours. The dermal dose of 2,000 mg/kg did not attain the LD_{50} for amitraz. This dose did incite a mild irritation producing slight erythema and edema after 24 hours that was reversed by 72 hours. The EC formulation produced moderate dermal irritation, which was attributed to the petroleum solvent (BFC Chemicals, 1981).

Twenty-four male and female dogs were exposed to a single dose of 250, 1250, or 2500 ppm amitraz, equivalent to 16, 68 and 136 mg/kg of body weight applied over the whole body (Kakuk and Weddon, 1976). The animals were observed seven days post-treatment for clinical signs of toxicity. Dose related effects of sedation and hypothermia culminated within eight hours of the treatment. Blood glucose levels were slightly to moderately elevated in all dosage groups four hours post-treatment. All effects were transitory and returned to normal ranges within 24 hours of the treatment.

A human patch test with multiple 0.5-ml doses of the EC product applied per cm^2 of skin produced moderate irritation (BFC Chemicals, 1981). However, repeated exposures did not significantly alter the irritation intensity, which was probably due to the petroleum solvent.

DERMAL ABSORPTION

A dermal absorption study of ^{14}C labeled amitraz in rats was conducted by Hazelton Europe in compliance with US Good Laboratory Practice standards and the UK Principles of Good Laboratory Practice (Stewart, 1993). Adult male rats were obtained from the Charles River (UK) Ltd. colony and acclimatized for about one week. One to two days prior to the study, an area of the dorso-lumbar skin was shaved and washed with acetone. A silicone ring was attached to the shaved area that provided approximately 10 cm^2 of skin surface available for exposure. The nominal doses were administered in a suspension of amitraz formulation and deionized water at 0.1, 1.0 or 10 mg of amitraz per animal equivalent to 10, 100, and 1,000 ug/cm^2. The treatment sites were protected with nonocclusive covers. After dosing, the rats were placed in individual all-glass metabolism cages suitable for the separate collection of the urine and feces. Four animals were used per sacrifice time per dose. Daily urine and feces samples were collected and analyzed separately. The animals in each dose group were exposed to their doses for 0.5, one, two, four or ten hours. After the exposure period the rats were sacrificed with the exception of the rats exposed for ten hours. These animals had their dose removed by swabbing with detergent soaked swabs and they were kept alive an additional 14 or 110 hours. The samples

collected for analyses were: nonocclusive covers, back washings, treated skin sites, cage washings/debris, blood, carcasses, feces, and urine.

Total recovery of the applied radioactivity ranged from 85-124% for all animals with the majority of the radioactivity (81-117%) recovered from the dose dressing and the wash-off solution. The highest percentage of the dose present at the application site after wash-off was 12.1 % at the four-hour sacrifice for the low dose animals. The percent of the dose present at the treated skin sites after wash-off for the medium and high doses was also highest four hours after administering the dose. Table I lists the results from analysis of the urine and feces samples collected following the 10 hour exposure period for the three dosage groups. The absorbed amitraz was excreted primarily in the urine with the rate of excretion decreasing with time. For all dose groups, the rate of excretion of the radiolabel in the urine and feces appears to plateau at about five days. The results indicate the dermal absorption rate of amitraz is dose dependent. A greater percentage of the low dermal dose (10 ug/cm^2) is excreted in the urine and feces than the 100 and 1,000 ug/cm^2 doses.

To calculate a rate of dermal absorption, the values from Table I for the 10-hour exposure period and the 120-hour sacrifice time were used. The cumulative value for the percentage of the dose detected in the urine and feces after 120 hours was corrected for the residues of amitraz that may still be present at the skin application site and is bioavailable. This correction was derived by employing an exponential saturation model with lag time to estimate the asymptote for the curve of the accumulative dose excreted versus time. An equation representing this model is: Y = A*(1-EXP(-B*(X+C))) or Recov = Max*(1-EXP(-Rate*(Time + Lag))). An example of the plots for the low dose and the outputs are shown in Figure 1. The corrected cumulative excretion in the urine and feces in conjunction with the amitraz detected in the blood, carcass, cage wash was used to estimate the rates of dermal absorption in Table II. These values were then corrected for the average percent recovery of the radioactivity for the appropriate dose group and sacrifice time to derive the final estimate of the dermal absorption rates.

Since the rate of dermal absorption for amitraz is dose dependent, the rate used to calculate the absorbed daily dose from an occupational exposure should be derived from a dose that is representative of the occupational exposure. The dermal exposures observed in the orchard air-blast exposure study (Castro and Ramos, 1988) averaged 3.8 ug/cm^2 for the hands and 4.7 ug/cm^2 for the body regions excluding the head and neck. In the surrogate exposure study used to estimate the exposure for aerial applicators (Maddy *et al.*, 1979), the dermal exposure ranged from 0.16 ug/cm^2 for the pilots to 0.54 ug/cm^2 for the mixer/loaders. The occupational exposure from applications of Taktic® to livestock was estimated from a study of cyromazine applications in a poultry house (Haskell *et al.*, 1993). The rate of exposure to the workers was dependent on the type of application equipment used with backpack sprayers experiencing the highest exposure rates at 0.88 ug/cm^2. In recognition of these observed and estimated rates of occupational dermal exposure, the 13.8% value derived from the rats dosed at 10 ug/cm^2 is the appropriate dermal absorption rate.

Table I. Percent dose of amitraz excreted following 10-hour exposure.

A. 0.1 mg/animal (10 ug/cm^2)

	Percent dose (mean)				
Time (h)	Urine (U)	Feces (F)	U + F		Cumulative
10	1.347	0.066	1.413		1.41
24	3.157	0.541	3.698		5.11
48	2.006	0.586	2.592		7.70
72	1.331	0.602	1.933		9.64
96	0.551	0.294	0.845		10.48
120	0.297	0.214	0.511		10.99
Total	8.689	2.303	10.992		

B. 1 mg/animal (100 ug/cm^2)

	Percent dose (mean)				
Time (h)	Urine (U)	Feces (F)	U + F		Cumulative
10	0.572	0.061	0.633		0.63
24	1.487	0.097	1.584		2.22
48	1.564	0.307	1.871		4.09
72	0.623	0.357	0.98		5.07
96	0.313	0.188	0.501		5.57
120	0.154	0.081	0.235		5.80
Total	4.713	1.091	5.804		

C. 10 mg/animal (1000 ug/cm^2)

	Percent dose (mean)				
Time (h)	Urine (U)	Feces (F)	U + F		Cumulative
10	0.115	0.021	0.136		0.14
24	0.681	0.267	0.948		1.08
48	0.771	0.341	1.112		2.20
72	0.479	0.21	0.689		2.89
96	0.257	0.137	0.394		3.28
120	0.191	0.153	0.344		3.62
Total	2.494	1.129	3.623		

Table II. Summary: Dermal absorption of amitraz in male rats*a.

Dose	Percent dose (mean)*b						
(ug/cm^2)	Excreted*c	Blood	Carcass	Cage wash	Sub-total	Recovery(%)	Total abs.*d
10	11.36	0.02	0.24	1.41	13.03	94.2	13.83
100	6.17	0.02	0	0.74	6.93	104.4	6.64
1000	4.06	0.01	0.8	0.52	5.39	95.1	5.67

*a Based on 10-hour exposure time and 120-hour sacrifice time.

*b Percent doses: excreted + blood + carcass + cage washings/debris.

*c At asymptote using an exponential saturation model.

*d Adjusted to reflect 100% recovery.

The results from the Hazelton Europe Laboratory dermal absorption study are supported by a similar study conducted by Challis (1990) with one dosage rate. In this study, rats were dosed at one mg per animal, equivalent to 91 ug/cm^2, with an aqueous dosing solution of ^{14}C-labeled amitraz suspended in the Mitac® formulation. After ten hours the dose was removed with tissue paper moistened with soap and water. Urine and feces were collected at 24-hour intervals after the start of the treatment. At 24 hours after treatment, five animals were sacrificed and the remaining five were maintained in metabolism cages for five days and then sacrificed. At sacrifice, the excreta, tissues, application site apparatus and dressings, application site skin, and the carcass with the gastrointestinal tract were analyzed for radioactivity. An additional two rats were given a single oral dose of 0.1 mg of amitraz in corn oil and maintained for 24 hours during which their urine was collected for analysis.

The percent of the dose detected in the excreta, cage wash, carcass and gastrointestinal tract was considered absorbed. A 6.6% dermal absorption rate was derived as the sum of the percentage excreted after 120 hours and the percentage detected in the gastrointestinal tract and carcass at sacrifice. Since the curve derived from plotting the accumulative excretion (urine and feces) over the five-day period approaches the maximum level of excretion, the 1.4% of the dose bound to the application site was not considered bioavailable.

An earlier study conducted by the FBC Limited Laboratory (Essex, England) in 1984, involved the treatment of pigs with ^{14}C-labeled amitraz (Campbell and Needham, 1984a) was reviewed. However, some of the parameters and the results of the pig study limit its value for use in estimating the rate of dermal absorption of amitraz in humans. Since only four animals were used in the study, the sample size may not be large enough to be representative. The dosage rate of 180 ug/cm^2 is two orders of magnitude greater than the exposure rates estimated in the worker exposure studies through biomonitoring. Almost 30% of the dose remained bound to the skin after wash-off. Without adequate excretion data, this percentage of the dose would be assumed to be absorbed following the Procedure for Studying Dermal Absorption (U.S. EPA, 1987b). The range of total recoveries (74-95%) for the animals indicates there may have been some problems with the analytical methodology.

ANIMAL METABOLISM

The metabolic fate of amitraz has been studied in several different test species at the FBC Limited Laboratory in England (Hornish and Nappier, 1983), (Campbell, 1984a). Although details of the recoveries from the spiked samples were not described, the total recovery from the urine and feces samples averaged better than 90 percent. The theoretical metabolic pathways are outlined in the metabolic flow diagram located after the references.

Administered as an oral dose, ^{14}C-labeled amitraz is rapidly excreted, primarily in the urine. The following percentages (means) of the dose were excreted in urine 24 hours after administration: dog-48.4%, mouse-57.6%, baboon-64.8% and rat-74.9%. These figures include the peak levels

of radioactivity in the urine. Peak levels in the blood of mice and dogs, following an oral dose, occurred within 1.5-6 hours.

Of the various species, the baboon accumulated the highest percentage of an oral dose in the tissues (Campbell, 1984b). The following concentrations of radioactive residues (mg equivalents per kg of fresh tissue) were detected 72 hours after a single dose at 10 mg/kg; liver (4.64-5.11 ppm), bile (2.17-2.93 ppm), whole eye (1.01-1.56 ppm), adrenal gland (0.25-0.72 ppm) and kidney (0.57-0.62 ppm). There were only minor differences in the excretion rates between the male and female of each species.

A mouse study compared the metabolic fate of ^{14}C-labeled amitraz fed to mice for three weeks versus those fed a normal diet (Campbell and Needham, 1983). All animals were then administered a single oral dose of 20 mg/kg of body weight of ^{14}C-labeled amitraz. The pre-exposure had little effect on the magnitude or distribution of the tissue residues. In both test groups, average residues were highest in the liver (0.5 ppm) and adrenal glands (0.45 ppm) and lowest in the bone (0.06 ppm) and muscle (0.04 ppm).

Two human male volunteers were given a single oral dose of 0.25 mg/kg of ^{14}C-labeled amitraz (Campbell and Needham, 1984b). Excretion in the urine was measured over a 72-hour period. Seventy-eight percent of the dose was excreted during the first 48 hours with 82% excreted during the test period. This excretion rate is comparable to those of the test animals.

A metabolic fate study was conducted on rats administered orally, one, 10, 50 and 100 mg/kg dosages of ^{14}C-labeled amitraz (Campbell and Needham, 1984c). Urine samples were collected for 24 hours after administering the doses and were used for identifying and quantifying the metabolites. The study focused on the excreted urine from the 100-mg/kg dosage. Results from the other dosages were used to characterize the identity and quantity of the metabolites at these dosages.

Essentially all of the dose was rapidly hydrolyzed in the stomach. In the urine, N-(2,4-dimethylphenyl)-N-methyl formamidine (BTS-27271), 2,4- dimethylformanilide (BTS-27919), 4-amino-3-methylbenzoic acid (BTS-28369), 4-formamido-3-methyl benzoic acid (BTS-39098), 4-acetamido-3-methyl benzoic acid (FBC-31158) and N-2,4-dicarboxyphenyl-N'-methyl formamidine (Metabolite A) were isolated by TLC and/or HPLC and confirmed by mass spectroscopy (Campbell, 1984a), (Campbell, 1984b). Traces of 2,4-dimethylaniline (BTS-24868) were evident by TLC in the urine, but they were too volatile to identify further.

At the 100 mg/kg dose level, each of these metabolites accounted for 1% or more of the radioactivity in the urine; BTS-27271 (23.0-29.0%), BTS-27919 (0.9-1.9%), BTS-28369 (0.3-1.2%), BTS-39098 (11.0-12.7%), FBC-31158 (16.5-19.1%) and the highly polar metabolites 40.2%. The highly polar fraction consisted of conjugates of BTS-28369, BTS-39098, FBC-31158, and BTS- 27271. These labile conjugates and the free BTS-39098 and FBC-31158 are converted to BTS-28369 by acid hydrolysis.

At all dose levels, BTS-39098 and FBC-31158 were major metabolites, accounting together for up to 31.8% of the excretion in urine. The excretion of BTS-27271 was dose dependent. At one mg/kg of body weight, only 4% of the dose was excreted as BTS-27271. BTS-24868 has been described as an intermediate metabolite that forms immediately after ingestion of an oral dose (Campbell and Needham, 1984c). Rats administered a 100 mg/kg oral dose excreted an average of 0.4% of the dose as BTS-24868 in the urine. When given a one and 10 mg/kg dose, the percent of BTS-24868 excreted in urine averaged one percent or less of the administered dose. BTS-24868 is then thought to breakdown to 4-amino-3 methylbenzoic acid in vivo.

The excretion of the metabolite BTS-27271 was found to be dose dependent in the tested animals (Campbell, 1984a). With an increase in the dose, the proportion of the urine that consisted of BTS-27271 also increased. The researchers theorized that amitraz is rapidly hydrolyzed to BTS-27271. BTS-27271 is then metabolized by an enzymatic process, which is easily saturated by high dosages. The excretion of amitraz metabolites in urine was investigated in rats, mice, baboons and humans (Campbell, 1984a). The spectrum of metabolites was qualitatively similar for all species tested and unaffected by sex or pre-exposure to amitraz. Mice, rats, and baboons were given a 10 mg/kg oral dose of ^{14}C-amitraz. The listed metabolites made up these percentages of radioactivity in the cumulative 24 hour urine sample; BTS-27919 [1.5% (rat)-1.9% (baboon)], BTS-28369 [1.9% (rat)-2.7% (baboon)], BTS-27271 [3.9% (rat)-5.4% (mouse)], BTS-39098 + FBC-31158 [17.2% (mouse)-26.5 (rat)], and polar material [53.4% (baboon)-61.8% (mouse)]. Humans were administered a 0.25 mg/kg oral dose and the urine was collected over a 96 hour period (Campbell, 1984a). These metabolites accounted for the following percentages of radioactivity in the urine; BTS-27919 (3.6%), BTS-28369 (3.8%), BTS-27271 (5.8%), BTS- 39098 + FBC-31158 (27.1%), and the polar materials (56.9%).

The EPA has concluded that 2,4-dimethylaniline (BTS-24868), one of the intermediate metabolites of amitraz, may pose an oncogenic risk to man (U. S. EPA, 1979). The results from a National Cancer Institute mice-feeding study were interpreted to exhibit a statistically significant increase in the incidence of pulmonary tumors. The EPA review of the Ames test results indicated a positive mutagenic response in one strain of bacteria had occurred (U. S. EPA, 1979). The Boots-Upjohn Company, owner of the amitraz product at that time, rebutted these EPA reviews.

Another study compared the metabolism of amitraz and BTS-27271 administered orally to white rats (Knowles and Benezet, 1981). Both amitraz and BTS-27271 were rapidly metabolized and eliminated primarily in the urine. In comparison to amitraz, a higher percentage of the BTS-27271 dose was eliminated in urine with an accompanying decrease in the feces. The degradation products of BTS-27271 detected in rat urine were similar to those found from metabolized amitraz.

The Upjohn Agricultural Research and Development Laboratories conducted an absorption and metabolism study on dogs dosed orally and dermally with ^{14}C-labeled amitraz (Hornish and Nappier, 1983). Oral absorption was rapid with nearly 80% of the dose excreted during the first 24 hours, primarily in the urine. The maximum blood levels from an oral four mg/kg dose were reached within eight hours post-treatment, ranging from 0.666-1.165 ppm (amitraz equivalents)

for five animals. Dermal absorption of a 20 mg/kg dose was much slower. Peak blood residue levels of 0.016-0.030 ppm (amitraz equivalents) were detected 24-168 hours post-treatment in four animals. After 9-11 days of exposure, 24-40% of the dermal dose had been excreted with the urine accounting for 75-89% of the excreted activity.

Whether administered as an oral or dermal dose, amitraz is metabolized essentially the same in dogs. The predominant metabolite in blood and urine is three-methyl-4 (N-formylamino)-benzoic acid (BTS-28369). The parent compound and the first-formed hydrolysis products were never observed at measurable levels in the blood and urine.

OCCUPATIONAL EXPOSURE

I. Orchard Air-Blast Operators

An orchard applicator exposure study was conducted by Hacker (1992) to measure the metabolites of absorbed amitraz that are excreted in urine and to quantify occupational exposure. Each operator (n = 7) was observed while mixing/loading and applying eight loads to pears with an air-blast sprayer at the maximum label rate of 1.5 lbs. a.i. per acre. The workers wore long pants and long-sleeved shirt underneath disposable coveralls, shoes or rubber boots, goggles and rubber gloves. Urine samples were collected for analysis 120 hours before the first exposure and for 120 hours after exposure to amitraz began. The urine samples were stored for an extended period of time (148-370 days) before analysis. The results from the extended storage stability studies were preliminary at the time of study submission and were not included. The rate of excretion of the metabolites in urine was determined by the conversion of the total urinary excretion (primarily FBC-31158, BTS-39098, and other conjugates) to BTS-28369 by acid hydrolysis and subsequent analysis for BTS-28369. A separate study in rats quantified this treatment to be 87% efficient in converting the total urinary excretion to BTS-28369 (Campbell and Needham, 1984c).

The urine analysis indicated the mean urinary excretion of amitraz metabolites for the workers applying Mitac® WP was 0.28 mg for the first 24 hours and 0.51 mg for the five-day period. Most of the operators excreted the largest portion of the metabolites during the first 24-hour interval after the start of the applications. To estimate what percentage of the absorbed dose of amitraz this value (0.51 mg) represents the human study by Campbell and Needham (1984b) was utilized. Eighty-two percent of a 0.25 mg/kg ^{14}C-labeled oral dose of amitraz was excreted as metabolites in the urine of two adult males over a 72-hour period. This excretion pattern is supported by observations made in animal exposure studies. In the pig, 6.7% of a dermally applied dose of ^{14}C-labeled amitraz was considered absorbed after 12 hours with 93% of the radioactivity associated with metabolites in the urine after a 60-hour excretion period (Campbell and Needham, 1984a). In the rat, 73% of the absorbed dermal dose was excreted as metabolites in the urine (Challis, 1990). The adequacy of the biomonitoring period (120 hours) for capturing the excretion of the absorbed dose is supported by the results from the same rat study. The accumulative excretion of the absorbed dose in urine and feces was considered 90% complete after 96 hours.

The identities of the metabolites in human urine and their relative percentages of the total excretion are similar to those identified in rats, mice and the baboon (Campbell 1984a). The polar fraction which comprised 60% of the excretion has been identified in rats to consist mainly of conjugates of FBC 31158, BTS-27271, BTS-39098 and BTS-28369 (Campbell and Needham, 1984b). The high percentage of the dose excreted in the urine and the observation that the parent compound was not detected in the urine indicates the oral dose was well absorbed and the metabolism is relatively complete. To correct for the percent of the radiolabeled dose that may have been excreted in the feces, lost during analysis or clean up or that remained in the tissues, the cumulative (5 days) urinary excretion from the biomonitoring study was divided by 0.82 (Campbell and Needham, 1984b).

In the exposure study by Castro and Ramos (1988), the operators mixed, loaded and applied an average of 14 loads per workday. The eight loads applied during the Hacker study represent 57% of the exposure the operator would be expected to receive during a full workday. To estimate the absorbed daily dose of amitraz from a full workday, the values in Table III were divided by 0.57.

Table III. Occupational Exposure to Amitraz for Operators in Pear Orchards

Operators[a]	Absorbed Daily Dosage (mg/workday)	Absorbed Daily Dosage[b] (ug/kg/day)	Annual Average Daily Dosage[c] (ug/kg/day)	Lifetime Average Daily Dosage[d] (ug/kg/day)
Mix/Load/Apply (N=7)				
mean (arith)	1.09	14.4	0.39	0.21
low	0.24	3.2	0.087	0.046
high	1.95	25.7	0.70	0.37

Haskell, WH&S, 1994·

[a] Operators mixed, loaded and applied 1.5 lbs. of active ingredient per acre with 400 gallons of water. The operators wore long-sleeved shirt and long pants underneath coveralls, goggles and rubber gloves.

[b] Calculated with a body weight of 76 kg for the worker.

[c] The staff of the Agricultural Commissioners offices for Lake and Sacramento Counties estimated 10 exposure days will occur annually.

[d] Calculated on the basis of a 75 year life span with 40 years of employment.

The results from the biomonitoring exposure study are supported by the observations made in a previous study of operators applying amitraz in a pear orchard. The Nor-Am Chemical Company completed a mixer/loader/applicator exposure study for Mitac® 50 WP in 1988 (Castro and Ramos, 1988). Mitac® 50 WP was applied with an air-blast orchard sprayer at the maximum recommended rate of 1.5 lbs. of a.i. per acre with 400 gallons of water. Typical for many orchard operations, one person performed the mixing, loading and application activities. Each operator wore at least the minimum protective clothing required by the label at that time; long-sleeve shirt, long pants, rubber gloves and boots. However, current Mitac® labels require workers to

wear the following additional protective clothing; coveralls over work clothing, protective eyewear, chemical resistant headgear and a chemical resistant apron during mixing and loading. Exposure was determined through passive dermal dosimetry (gauze patches) exposed directly to field conditions, hand washes, micro air pumps and urine testing.

The study was designed well and the results from the field study were presented in detail. Six operators mixed, loaded and sprayed 13 to 17 loads per day each, applying 19 to 25.5 pounds of active ingredient. Residues detected under the protective clothing averaged 82±36 mg (range 37-130). Exposure to the hands was minimal with a mean of 3.2±1.86 mg (range 0.23-5.12) detected. The mean inhalation exposure was 0.61±0.14 mg (range 0.48-0.84) for the 6 operators. These exposure rates probably represent an over estimation of the occupational exposure to amitraz because the current Mitac® label requires additional protective clothing to be worn by workers.

The results from the biological monitoring section of the mixer/loader/applicator exposure study are very similar to those observed in the Hacker (1992) study. The mean cumulative amount of amitraz equivalents detected in the human urine, 48 hours after the onset of the application exposure, was 0.39 mg. This figure, however, must be corrected for the percent recovery (76%) of the analyte BTS-28369 from the lab-fortified urine sample and then standardized for an 8-hour exposure period. The corrected value (0.61 mg) for the amitraz equivalents excreted in urine is within the range observed in the Hacker (1992) study.

Exposure studies utilizing patch dosimetry to observe dermal exposure have the tendency to overestimate exposure through the assumption that exposure is consistent within the body area represented by each patch. Many body regions (back, undersides of arms, back of legs) are partly protected from exposure by their orientation to the exposure activity. In conjunction with the exposure data, a rate of dermal absorption has to be estimated to calculate the absorbed dose. This rate is usually derived from an animal study with the assumption that the human rate is similar although human dermal absorption is typically much lower. Rates of clothing penetration may also have to be factored into the dermal exposure estimate. Because the metabolism of amitraz and the excretion of the metabolites are known quantitatively and qualitatively, the exposure data from the biomonitoring studies provided the most accurate determination of occupational exposure.

II. Field Crop Application

The Nor-Am Chemical Company has recently registered a new liquid formulation of amitraz, Ovasyn®, for use on cotton to control mites and other insect pests. Treatments can be made from the time the plants are 4-6 inches in height until the bolls start to open. Initially, the product was designated as a category II pesticide. However, since the current label is now designated as a category I pesticide, California regulations require Ovasyn® to be mixed and loaded with a closed system. Additional exposure data was not submitted to support this new use. The registration of amitraz on cotton represents a major new use that can incur exposure for handlers, flaggers and field checkers. Applications for early season mite and worm control (April-June) are expected to be made by growers with ground equipment (Goodell, 1993). Later in the season

(June-August), treatments for white flies and worms will be made by aircraft. Data from surrogate studies were used to estimate the occupational exposure from applications to cotton.

A. Ground Boom Application

A study of the occupational exposure incurred from applying oxydemeton-methyl (Meta-Systox R®) to vegetables was used as a surrogate study to estimate the exposure from applying Ovasyn® to cotton with a boom equipped tractor (Oshita *et al.*, 1988). The application rate, formulation type and type of application equipment were similar to applying Ovasyn® to cotton. Since oxydemeton-methyl has a much higher vapor pressure than amitraz, the observed inhalation exposure is expected to be much greater than for amitraz. The Meta-Systox R® formulation of oxydemeton-methyl was applied at a rate of 0.5 to 0.75 lb. a.i. per acre to cabbage, broccoli, cauliflower, and Brussels sprouts, using tractors equipped with boom sprayers or aircraft. Eleven workers were monitored for dermal and inhalation exposure during 24 workdays. Each worker wore a shirt, long pants, socks, and cloth coveralls. Additional protective clothing, consisting of chemical resistant gloves, boots, rainsuit or standard Tyvek® coveralls, hat, respirator, and a face shield or goggles, were worn to comply with the permit conditions for applying oxydemeton-methyl. The mixing/loading operation was conducted with a closed system. This protective clothing regime and the closed mixing/loading system approximates the requirements on the current Ovasyn® with the exception of the use of a respirator, chemical resistant coveralls, and hat. However, the Ovasyn® label requires three layers of clothing for some regions of the body (work clothes, coveralls and chemical resistant apron) which will compensate for this difference. The respirator was worn solely for protection and did not effect the monitoring of the air levels for oxydemeton-methyl.

Surgical gauze patch dosimeters were placed at several locations both under the cloth coveralls (protected) and on the outside of the rainsuit (unprotected). Hand exposure was measured using hand washes and knit nylon gloves worn underneath the chemical resistant gloves. The chemical resistant gloves were worn during mixing/loading but not during application. Personal air sampling pumps were worn by the workers to sample the air concentration of oxydemeton-methyl in their breathing zone. There were four applications made with a tractor with an enclosed cab, 17 applications made with tractors with open cabs and three applications were made with aircraft. The residues detected on the patch dosimeter represented the exposure per cm^2 that occurred to that region of the body. A body surface area of 17,689 cm^2 (excluding the hands) was used to calculate the dermal exposure for an adult male (Popendorf and Leffingwell, 1982).

The dermal exposure to the worker was estimated from the residues detected on the protected dosimeters. Most of the dosimeters located under the protective clothing had no detectable residues. Dosimeters with no detectable residues were assumed to have residues at 1/2 the minimum detectable level (MDL = 0.2 ug/sample). Exposure was expressed as the dermal exposure per hour of work or the exposure per pound of a.i. applied. The mean (arithmetic) exposure rate for an operator mixing/loading and driving a tractor with an open cab was 39.8 ug of dermal exposure per pound of a.i. applied. The values for the shoulders, forearms and shins were doubled to account for the difference in protection between cloth coveralls and chemical resistant coveralls. The mean value listed in Table IV was derived with the assumption that a

grower would treat 100 acres of cotton per day at the maximum label rate (1.0 lb. a.i./acre). Only six of the 24 exposure periods monitored for air levels of oxydemeton-methyl had detectable levels (0.76 ug/m^3 to 4.8 ug/m^3). As the vapor pressure of oxydemeton-methyl is approximately 75X greater than amitraz, the inhalation exposure when respirators are worn was considered miniscule.

B. Aerial Application

Maddy *et al.* (1979) conducted a study monitoring the occupational exposure for pilots, mixer/loaders and flaggers applying tributyl phosphorotrithioate (DEF®) and tributyl phosphorotrithioite (Folex®) to cotton in the San Joaquin Valley. The employees of two aerial application PCOs were monitored for dermal and inhalation exposure while treating 1,000 acres per day at a rate of 1.32-1.50 lbs. a.i. per acre. This would be considered a maximum exposure work schedule.

Each company utilized a closed system to mix the pesticide batches and load them into the airplanes. The workers wore work clothes and the designated protective clothing for the following tasks: mixer/loader-overalls, rubber gloves, rubber apron (company two only) boots and cap; pilots-helmets; and flaggers-coveralls and caps. These protective clothing regimes approximate the protective clothing required on the Ovasyn® label for mixer/loaders and pilots with the exception of the requirement for mixer/loaders to wear protective eyewear and the pilots to wear chemical resistant gloves when entering and exiting a contaminated aircraft. However, federal and California regulations consider flagging to be a work task that is included in the definition of "handlers" or "handling". As flaggers will be exposed to the diluted pesticide, they are required to wear coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear plus socks, protective eyewear and chemical resistant head gear.

Dermal exposure was measured with the use of two layered patches (outer layer-cloth, inner layer gauze) attached on the outside of the worker's clothing. Exposure for the exposed areas (face, neck) was calculated as the sum of the residues detected on both patches. Exposure for protected body regions (arms, torso, legs) was derived from the amount of residues detected on the gauze layers. The hands were rinsed with ethyl alcohol at the end of the work shift to determine hand exposure. Inhalation exposure was measured with an air pump that drew air through sampling tubes at a flow rate of 0.2 L/minute. Six workdays were monitored with the following number of replicates for each work task: mixer/loader (10); pilot (11); and flagger (11).

A mean dermal exposure rate per pound of a.i. applied was derived from Table VI of the study (Maddy *et al.*, 1979) for the following work tasks: 11.4±7.60 µg-mixer\loader; 6.18±2.63 µg-pilot; and 7.95±5.97 µg-flagger. For inhalation the mean exposure rates per pound of a.i. applied were: 0.37±0.30 µg-mixer\loader, 0.17±0.27-pilot and 1.01±1.85 µg-flagger. The pounds of amitraz handled per workday were calculated as treating 1,000 acres per day at the maximum label rate of 1.0 lb. a.i. per acre. The exposure rates from the surrogate study were then used to derive the exposure values for amitraz listed in Table IV. A second correction was necessary for the flaggers to account for the additional protective clothing (chemical resistant gloves and hat, coveralls, protective eyewear) required by the current Ovasyn® label. Exposure to the hands accounted for 39% of the dermal exposure, the body regions protected by coveralls accounted for

23% of the dermal exposure and the head, face and neck, 38% of the exposure (Maddy *et al*., 1984). Chemical resistant gloves and cloth coveralls can provide 90% protection (Thongsinthusak *et al.*, 1993).

C. Cotton Scouts

Many growers practice IPM to control insect pests in cotton. Growers contract pest control advisors (PCAs) to check their crop through the growing season for a cost per acre fee. PCAs or field checkers under their supervision can enter fields weekly to monitor insect populations and to determine the maturity of the crop. They average at most 6 hours per workday walking in the cotton fields with the remaining time spent completing paper work and driving from one ranch to another (Dong, 1990). The potential dermal exposure for field checkers checking amitraz treated cotton can be estimated if the DFR are known at the time of entry and a transfer factor (potential dermal exposure divided by the observed DFR) can be calculated for the work activity. A transfer factor of 11,610 cm^2/hour was derived for cotton scouts from the review of exposure studies for similar activities (Dong, 1990).

Data on the deposition and degradation of amitraz residues on cotton leaf surfaces were not submitted with the cotton registration request. However, a study was conducted on pear tree foliage in Washington State to determine the amitraz derived residues present after two applications of Mitac® WP (Brady, 1992). The applications were made 14 days apart at the maximum label rate of 1.5 lbs. a.i. per acre with the last treatment occurring 14 days before the normal harvest date. A DFR value of 0.69 ug/cm^2 was observed 24 hours after the second application. Since the maximum label rate for cotton is 1.0 lb. a.i. per acre, the estimated DFR one day after an application was reduced proportionally to 0.46 ug/cm^2. The 11,610 cm^2/hour transfer factor multiplied by the DFR of 0.46 ug/cm^2 from the pear study with a six-hour exposure period yielded a potential dermal exposure of 32.0 mg per day for field checkers scouting amitraz treated cotton. Assuming the work clothing worn by the field checkers provides 90% protection (Thongsinthusak, 1991), the estimated daily dermal exposure is 3.2 mg.

Although inhalation exposure to amitraz was not estimated for the cotton scouts, it is not likely to be a significant route of exposure. A study by Wolfe (1976) surveyed the results of many exposure studies for workers mixing, loading and applying a variety of pesticides in various formulations. As part of the total exposure for the worker, the inhalation component accounted for less than 1% (mean value) with a range of 0.1-3.1 percent for the studies reviewed.

Table IV. Occupational Exposure for Workers Making Applications Of Amitraz and Scouts Checking Amitraz Treated Cotton.

Work Tasks	Daily Dermal Exposure (mg/workday)	Daily Inhalation Exposure (mg/workday)	Absorbed Daily Dose[a] (ug/kg/day)	Annual Average Daily Dose[b] (ug/kg/day)	Lifetime Average Daily Dose[c] (ug/kg/day)
Ground Application					
mix/load/apply	3.98±2.35	N/A	7.23	0.32	0.17
Aerial Application					
mix/load	11.4±7.60	0.37±0.30	23.1	0.51	0.27
apply	6.18±2.63	0.17±0.27	12.3	0.27	0.14
flag	3.51±02.64	1.01±1.85	13.0	0.29	0.16
Cotton scout	3.2	-----	7.1	0.21	0.11

Haskell, WH&S, 1994.

N/A - Not available.

[a] Dermal absorption is 13.8% (Stewart, 1993). Inhalation absorption was considered as 50% uptake and 100% absorption (Raabe, 1988). The workers in the surrogate DEF® study were all males and the surface areas of the body regions used to extrapolate exposure were appropriate for male subjects. Therefore, the weight of a 76-kg man was used to calculate the Absorbed Daily Dose (Thongsinthusak *et al.*, 1993). However, since the exposure data for the cotton scouts was derived with a transfer factor whose source of exposure data could be male or female subjects, a 62 kg body weight was used for the cotton scouts (Thongsinthusak *et al.*, 1993).

[b] Custom ag-chemical applicators servicing cotton growers could make ground applications of Ovasyn® a maximum of 16 workdays per season (Huckins, 1994). The 8 annual application days for the mixer/loader, pilot and flagger were estimated from application data of an aerial applicator in the Southern San Joaquin Valley making August treatments of Curacron® to cotton. Cotton scouts were estimated to enter amitraz treated cotton fields for 11 workdays per season. This exposure scenario is estimated from mid-July through August applications of Ovasyn® to control white flies that cause "sticky cotton" and the assumption that 25% of the cotton acreage checked by the cotton scout on a weekly basis would be treated with Ovasyn®.

[c] Calculated on the basis of a 75-year life span with 40 years of employment.

IV. Livestock Treatment

Amitraz is registered under the trade name Taktic® for use as a spray, spray-dip application on beef and dairy cattle and pigs to control ticks, mites and lice. Applications to cattle are made as a mixture of one-two cans (25.7 oz. each) per hundred gallons of water (0.4-0.8% solution by weight). Each animal can be treated with a maximum of two gallons of spray mixture. Beef cattle are usually treated for lice and ticks in the summer and fall when they are moved off the dry land pasture or range for the season. Ranchers can pen the animals and then walk them single-file past a power sprayer operator that treats one side of the animal at a time. The process is repeated until the whole body of the animal is treated (Patterson, 1994). In feedlots animals are usually treated upon arrival and large numbers of animals are treated at one time. To facilitate the rapid treatment of the cattle for lice or ticks, most feedlot operators now use other active ingredients that can be injected into the animals (Norman, 1994). However, a few operators may utilize a squeeze chute equipped with nozzles to spray the whole animal with amitraz. Another method uses a hydraulic cage to dip the animal in the spray mixture. In the dairy industry, wide spread use of this product is not known. Dairy cattle rarely get ticks but lice and parasitic fly infestations can be a problem. The U.C. Cooperative Extension dairy specialist

indicates that treatments to control lice and ticks are usually made with "over-the-counter" products formulated with coumaphos or abamectin (Maas, 1994). Products that can be injected or poured directly on the animal are easier to use than products that need to be applied as a full coverage spray.

In swine production, applications of Taktic® can be used as a preventive treatment for infections of body lice. Swine and their pens are treated with a mixture of one can of product per 50 gallons of water (0.8% solution by weight). The adult pigs are treated with a coarse spray until run off while piglets or weaners can be dipped in the mixture. In commercial operations sows are bred twice a year and moved to the farrowing barn a few days before the anticipated birth (Farley, 1994). The sows remain there for 14-28 days after the birth to nurse the piglets. When they are removed from the farrowing barn, another set of pregnant sows is moved in to give birth. In most operations, sows can be present in the farrowing barns year round. Sows can be treated for body lice when they are moved to the farrowing barns to prevent infections from spreading to the soon-to-be-born piglets (Norman, 1994). A small farm operation with 250 sows, will move approximately 40 sows per month through the farrowing barn, with about 10 arriving per week (Farley, 1994). On small farms, applications are made with either a hand-held sprayer or backpack sprayer. On larger operations, some type of power sprayer is used to make the treatments. Assuming a sow has about one half the surface area of a cow, one gallon of spray mix (1/2 oz of Taktic® in one gallon of water) containing 0.0037 lb. of amitraz would be the maximum treatment per sow. Because of the intensive labor involved, the practice of dipping piglets in the mixture is seldom used.

To estimate the occupational exposure to amitraz from applications of Taktic®, an exposure study from the application of cyromazine in a poultry house was used. Larvadex® 2SL was applied to manure piles with a hand-held sprayer, a backpack sprayer and with a hand-held boom attached to a portable power sprayer with a long hose (Haskell *et al*., 1993). Each replicate consisted of mixing and applying a two-gallon mixture of 0.1% cyromazine three times. Nine replicates of each application method were conducted with 0.024 kg of a.i. applied per replicate. The study observed potential and actual exposure when workers wear a dust mask and rubber gloves in addition to work clothing (socks and shoes, long pants and long-sleeved shirt). This protective clothing regime approximates the label requirements for handling Taktic® with the exception of the requirement to wear goggles, a hat and boots and a chemical resistant apron when mixing/loading Taktic®. Dermal exposure was detected with patches attached outside the workers Tyvek® coveralls and with cotton gloves worn underneath the rubber gloves. Pesticide residues that penetrated the cloth covering of the patches were considered actual dermal exposure. A body surface area of 19,400 cm^2 was used to calculate the total dermal exposure from the patch dosimetry and the hand washes. Respiratory exposure was monitored during the exposure period with a personal air pump that drew air through two filters covered with the dust mask material. The flow rate through the filters was two liters per minute.

The mixing/loading of the portable power sprayer and the application of the mixture with a hand-held boom to the manure piles were considered separate tasks. Exposure was expressed in milligrams of dermal exposure per replicate and the workday exposure was derived from the number of replicates (14) that could be completed during an eight hour shift. The minimum

detectable level (MDL) for cyromazine on the patches was 0.001 ug/cm^2 and 0.2 ug total for the gloves and the foam filters. All the protected patches for the workers performing the mixing/loading work task had residues below the detection limits with the exception of one. Exposure was assumed to be 1/2 the MDL when dosimeters yielded non detectable residues. Most of the workers applying cyromazine with the hand-held boom portable power sprayer had detectable residues on the thighs, ankles and forearms. The estimated exposure to cyromazine when one worker performed both the mixing/loading and application work tasks for eight hours was 3.97 mg of dermal exposure and 0.05 mg of inhalation exposure.

The Larvadex® 2SL exposure study can be used to estimate the occupational exposure to amitraz from an application of Taktic®. The workers handled 2.46 lbs. of cyromazine per workday operating the power sprayer and experienced a combined total of 3.97 mg of dermal exposure and 0.05 mg of inhalation exposure. Assuming one worker performed both work tasks during the livestock treatments, the exposure rate was equivalent to 1.61 mg of dermal and 0.02 mg of inhalation exposure per pound of active ingredient handled. The exposure rates for the backpack sprayer were 31.6 mg of dermal and 0.032 mg of inhalation exposure per pound of active ingredient handled. The handheld sprayer experienced 0.66 mg of dermal and 0.033 mg of inhalation exposure per pound of active ingredient handled.

On a small cow-calf operation, one worker could be expected to treat about 50 cows per day with a power sprayer (average herd size in Siskiyou County-150 head) (Beck, 1994). However, on larger cow-calf operations, 200 animals can be treated per day using the directed spray method with penned animals (Patterson, 1994). At the maximum Taktic® label rates for cattle, approximately 0.0075 lb. a.i. is needed to treat one grown cow. The worker on the small cow-calf operation would handle 0.375 lb. of amitraz per workday (50 X 0.0075 lb. a.i. per cow) and experience an estimated 0.60 mg of dermal exposure and 0.0075 mg of inhalation exposure. The worker on the large operation would treat 200 cows per day and experience an estimated 2.42 mg of dermal exposure and 0.03 mg of inhalation exposure. Since feedlot applications are essentially mechanized, exposure to the operator is expected to be insignificant.

For swine production, a small farm operation may use a backpack sprayer to make the Taktic® treatments while a corporate operation would probably use the power sprayer. The estimated maximum label treatment for swine on the Taktic® label was 0.0037 lb. of amitraz per animal. The small farm operation may run 250 sows while a large corporate operation can manage 10,000 sows (Koenig, 1994). On the large operations, the sow populations are divided into management "units" of about 1200 animals with each unit having its own labor force. If the sows are treated each time they enter the farrowing barn, the number of sows moving into the farrowing barn each week can be estimated by dividing the herd size or "unit" size by 52 (52 weeks per year) and then multiplying this value by two (enter twice a year). This value multiplied by 0.0037 lb. a.i. will provide an estimate in the pounds of amitraz handled per workday. Utilizing the listed dermal and inhalation exposure rates per pound of amitraz handled, the estimates for the daily and lifetime occupational exposure to amitraz from livestock treatments were derived and listed in Table V.

Table V. Lifetime Occupational Exposure to Amitraz From Livestock Treatments

Type + Size of Operation	Daily Dermal Exposure (mg/workday)	Daily Inhalation Exposure (mg/workday)	Absorbed Daily Dose[a] (ug/kg/day)	Annual Average Daily Dose[b] (ug/kg/day)	Lifetime Average Daily Dose[c] (ug/kg/day)
Cow-calf operation					
small	0.60	0.0075	1.14	0.009	0.0048
large	2.42	0.03	4.59	0.16	0.085
Swine production					
small farm	1.17	0.0012	2.13	0.30	0.16
corp. farm	0.27	0.0034	0.51	0.07	0.037

Haskell, WH&S, 1994.

[a] Dermal absorption is 13.8% (Stewart, 1993). Inhalation absorption was considered as 50% uptake and 100% absorption (Raabe, 1988). The workers in the surrogate Larvadex® study were all males and the surface areas of the body regions used to extrapolate exposure were appropriate for male subjects. Therefore, the weight of a 76-kg man was used to calculate the Absorbed Daily Dose (Thongsinthusak *et al.*, 1993).

[b] The annual number of application days for the cow-calf operator was estimated by dividing the herd size (Siskiyou County average size 150 head, large operation 2500 head) (Beck, 1994) by the number of animals treated per workday (50 or 200). If both the small and large farm operations make one treatment each week, the annual number of application days for swine production was 52.

[c] Calculated on the basis of a 75 year life span with 40 years of employment.

V. HARVESTERS

Pears are normally harvested by hand and exposure to the harvesters must be considered in the exposure assessment. An exposure study for harvesters has not been conducted for amitraz. However, an estimate of dermal exposure can be made if the dislodgeable foliar residues (DFR) at the time of harvest are known and a transfer factor (dermal exposure per worker in ug/hour divided by the DFR) can be estimated for the particular work activity.

The deposition and degradation of amitraz residues on leaf surfaces has been studied. In 1991, a study was conducted on pear tree foliage in Washington State to determine the amitraz derived residues present after two applications of Mitac® 50 WP (Brady, 1992). The applications were made 14 days apart at the maximum label rate of 1.5 lbs. a.i. per acre with the last treatment occurring 14 days before the normal harvest date. Foliage samples, consisting of 40 one-inch diameter leaf punches (405 cm^2 total surface area) each, were taken just prior to the first application and at 0, 1, 2, 5, 7, 14, 21, 28 and 35 days after the last treatment. Three samples of treated foliage and a untreated control sample were taken at each time interval. Foliage samples were spiked in the lab, frozen and shipped to the field trial site. The spiked samples of either amitraz, BTS-27271 or BTS-27919 were then included with the field and control samples at each of the sample intervals. All samples were put on dry ice and stored frozen in a field trial freezer until shipment to the analytical lab for extraction and analysis.

Analysis of all the samples was done at the NOR-AM Research center in North Carolina. The leaf discs were washed with buffered detergent solution and the rinsate partitioned with methylene chloride and evaporated to dryness. The dry residue was reconstituted with toluene and quantified by gas chromatography using a nitrogen specific detector. Samples were analyzed for the parent compound and two degradates, BTS 27271 and BTS 27919. Two "field spikes" and two spikes of the reagent used to wash the DFR off the leaf discs were analyzed for each set of leaf punch samples. The recovery of the reagent spikes averaged 98%. Recovery from the "field spikes" averaged 92.8% indicating the residues of amitraz and its degradation products were stable under the storage conditions.

The data indicate that the foliar residues of amitraz dissipate slowly. The regression of residues on time through the 35-day dissipation period yielded the following equation: $y = -0.25958 + (-0.02909\ x)$ where y = log (natural) of ug/cm^2 and x = days. Since the pre-harvest interval is seven days, a DFR of 0.63 ug/cm^2 was derived from the best-fit curve for the DFR dissipation through 35 days.

A transfer factor derived from exposure and DFR data can provide an estimate of the amount of foliage contacted per hour for workers hand-harvesting pears in an amitraz-treated orchard. A generic transfer factor was derived from three studies that observed the exposure to farm workers wearing work clothing and harvesting peaches in orchards treated with various pesticides (Table VII). The 4,023 cm^2/hour transfer factor was used in conjunction with the DFR of 0.63 ug/cm^2 from the amitraz study to calculate the dermal exposure for workers picking pears in an amitraz-treated orchard. The transfer factor times the DFR yields an estimated dermal exposure of 2,535 ug/hour or 20.3 mg/8-hour day. The respiratory exposure for the peach harvesters was minute, accounting for approximately four tenths of one percent of the total dermal exposure. This same observation has been made in other harvester exposure studies. Since the respiratory component of the total exposure is so small, it will be considered negligible for the pear harvesters.

Table VI shows the estimated exposure for harvesters working 8 hours per day in a pear orchard treated previously with 3.0 lbs. a.i. of amitraz per acre. The DFR are assumed to be 100% dislodgeable.

Table VI. Harvester Exposure to Amitraz in a Pear Orchard Treated with Amitraz.

Dermal Exposure (mg/8-hr day)	Absorbed Daily Dosage[a] (ug/kg/day)	Annual Average Daily Dosage[b] (ug/kg/day)	Lifetime Average Daily Dosage[c] (ug/kg/day)
20.3	36.9	3.64	1.94

Haskell, WH&S, 1993.

[a] Dermal absorption is 13.8% (Stewart, 1993). Inhalation exposure is negligible. Calculated for the weight of a 76-kg man (Thongsinthusak *et al.*, 1993).

[b] Calculated on the basis of 36 exposure days per year. Determined from discussions with staff of Lake and Sacramento County Agricultural Commissioners.

[c] Estimated lifetime exposure from picking pears for 40 years over a 75 year life-span.

VI. Veterinarians

A product is available for use by veterinarians to control tick infestations on dogs with collars impregnated with amitraz. The typical pet collar weighs one ounce and contains 9% amitraz by weight. Exposure to amitraz from placing the collar around the neck of the animal is expected to be miniscule due in part to the small dose of a.i. (2.6 gm) being handled. Data from research conducted for the federal registration of the Taktic® Dairy Collar indicate the release of amitraz from the polymer collar is less than 6% over a 90-day period under laboratory conditions (Nor-Am Chemical, 1991). The manufacturer recognizes this release rate could be enhanced by the abrasion of the cow's hair against the collar. Research from similar formulations indicates the maximum release rate over a 90-day period could be 20% of the a.i. present in the collar. Assuming the same release rate for the dog collar, 20% of the 2.6 gm of a.i. present in the collar could be available with an average of 5.8 ug present per day over the 90 day period. If the dog handler experienced the maximum dose of amitraz available while placing the collar on the animal with bare hands and treated five dogs per day, the absorbed daily dose (13.8% dermal absorption) would be 0.05 ug/kg/day for a 76 kg man.

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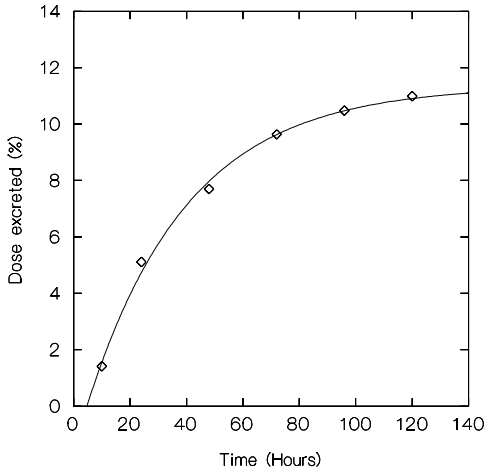
Figure 1. Asymptotic plot of percent dose excreted in urine and feces after topical administration of amitraz at 0.1 mg/animal (ca 10 µg/cm^2)

$$Y = 11.356*(1-EXP(-0.028*(X-4.738)))$$



Statistics:

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ITERATION	LOSS	PARAMETER VALUES		
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1	.3014362D+03	.6667D+01	.1067D+01	-.4833D+01
2	.6787968D+02	.7453D+01	.8223D+00	-.4994D+01
3	.4288598D+02	.8078D+01	.1604D+00	-.4593D+01
4	.1483351D+02	.8776D+01	.5133D-01	-.4969D+01
5	.6958837D+01	.1015D+02	.5252D-01	-.5953D+01
6	.5753622D+00	.1118D+02	.3192D-01	-.6662D+01
7	.4512091D+00	.1104D+02	.3220D-01	-.6561D+01
8	.4500136D+00	.1104D+02	.3225D-01	-.6565D+01
9	.4496657D+00	.1104D+02	.3224D-01	-.6562D+01
10	.4466517D+00	.1100D+02	.3214D-01	-.6468D+01
11	.4342199D+00	.1092D+02	.3254D-01	-.6168D+01
12	.3769090D+00	.1121D+02	.3089D-01	-.5815D+01
13	.2552073D+00	.1135D+02	.2848D-01	-.4920D+01
14	.2446734D+00	.1138D+02	.2785D-01	-.4646D+01
15	.2429564D+00	.1135D+02	.2816D-01	-.4748D+01
16	.2429082D+00	.1136D+02	.2811D-01	-.4737D+01
17	.2429066D+00	.1136D+02	.2811D-01	-.4737D+01
18	.2429065D+00	.1136D+02	.2811D-01	-.4738D+01
19	.2429065D+00	.1136D+02	.2811D-01	-.4738D+01

DEPENDENT VARIABLE IS RECOV

SOURCE	SUM-OF-SQUARES	DF	MEAN-SQUARE
REGRESSION	410.741	3	136.914
RESIDUAL	0.243	3	0.081
TOTAL	410.983	6	
CORRECTED	68.424	5	

RAW R-SQUARED (1-RESIDUAL/TOTAL) = 0.999
CORRECTED R-SQUARED (1-RESIDUAL/CORRECTED) = 0.996

PARAMETER	ESTIMATE	A.S.E.	LOWER <95%>	UPPER
MAX	11.356	0.357	10.218	12.493
RATE	0.028	0.003	0.018	0.038
LAG	-4.738	1.272	-8.785	-0.691

ASYMPTOTIC CORRELATION MATRIX OF PARAMETERS

	MAX	RATE	LAG
MAX	1.000		
RATE	-0.872	1.000	
LAG	0.479	-0.712	1.000

(TCW/Dermal/Amitrz1W)

Figure 2 Metabolism of a 100 mg/kg Body Weight Oral Dose of ^{14}C-Amitraz in Rats

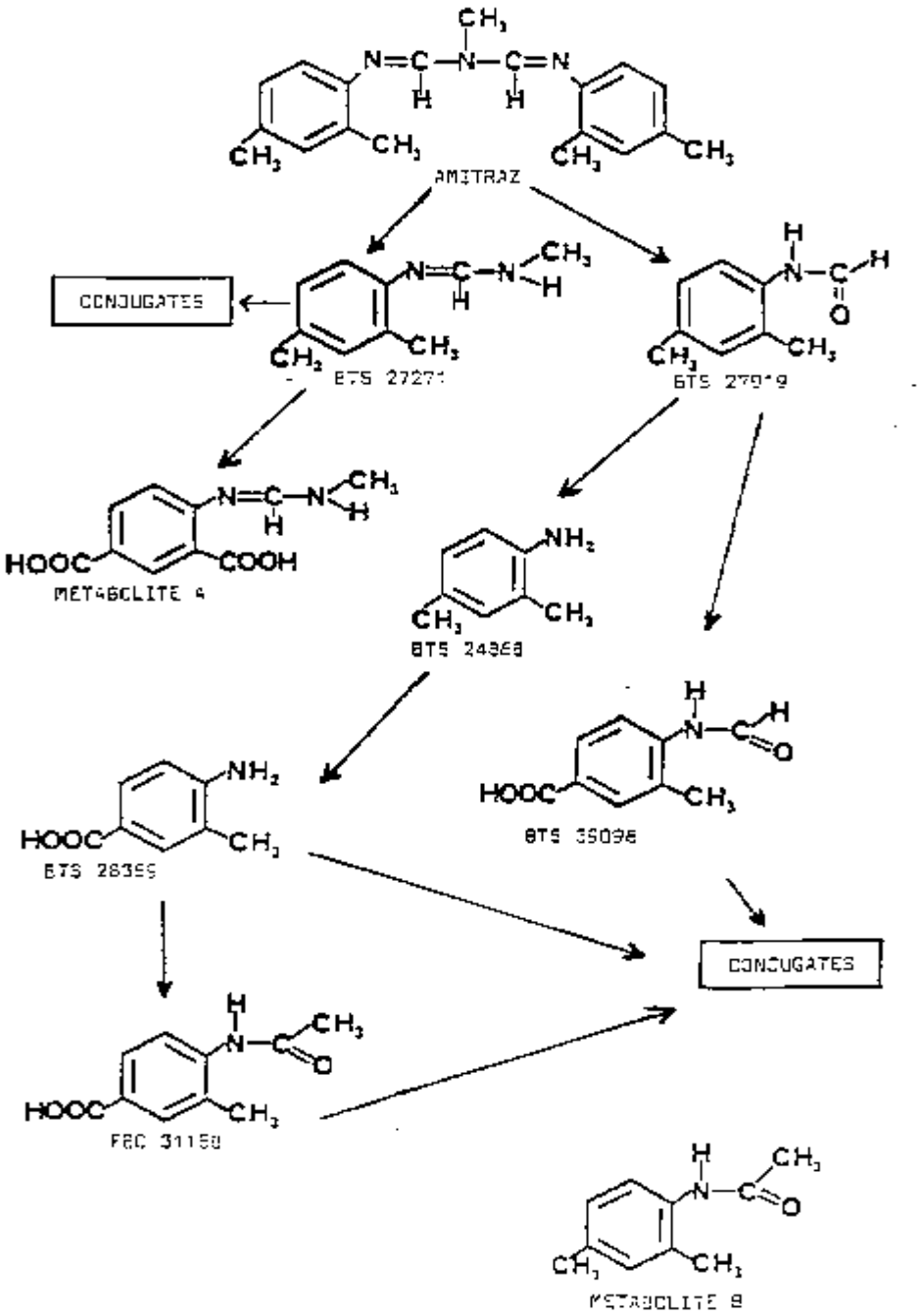

Table VII Estimation of a Generic Transfer Factor For Tree Crop Harvesters From Dermal and Dislodgeable Foliar Residue Data

Pesticide and year applied(a)	Crop and application site	No. of days post application(b)	Observed DFR (μg/cm2)(c)	No. of workers Monitored(d)	Mean dermal exposure per harvester (mg/8 hour workday)	Transfer factor for harvesters (cm2/hour)(e)	Total foliage contacted by all harvesters in crew (cm2/hour)(f)
Azinphos-methyl, 1989 (1)	Peaches Sutter County	32	0.66	ten	15.6	2958	29,600
Azinphos-methyl, 1989 (1)	Peaches Sutter County	33	0.62	ten	15.5	3,119	31,200
Azinphos-methyl, 1990 (1)	Peaches Sutter County	52	0.36	eleven	12.0	4,174	45,900
Azinphos-methyl, 1990 (1)	Peaches Sutter County	53	0.61	eleven	14.0	2,877	31,600
Azinphos-methyl, 1989 (1)	Peaches Stanislaus County	60	0.009	eight	0.44	6,111	48,900
Azinphos-methyl, 1989 (1)	Peaches Stanislaus County	61	0.011	nine	1.25	14,205	127,800
Azinphos-methyl, 1989 (1)	Peaches Stanislaus County	62	0.07	eight	4.30	7,679	61,400
Phosmet 1989 (1)	Peaches Stanislaus County	34	2.5	eight	28.17	1,409	11,300
Phosmet 1989 (1)	Peaches Stanislaus County	35	2.5	eight	31.6	1,579	14,200
Phosmet 1989 (1)	Peaches Stanislaus County	36	2.5	eight	39.3	1,964	15,700
Phosalone 1976 (2,3)	Peaches Stanislaus County	13-15	2.90	six (4)	76.0	3,276	19,700
Phosalone 1977 (2,3)	Peaches Stanislaus County	7-9	3.59	six (4)	67.2	2,340	14,000
Phosalone 1977 (2,3)	Peaches Stanislaus County	22-24	0.90	six (4)	57.2	7,944	47,700

Table VII(cont) Estimation of a Generic Transfer Factor For Tree Crop Harvesters From Dermal Exposure and Dislodgeable Foliar Residue Data

Pesticide and year applied(a)	Crop and application site	No. of days post application(b)	Observed DFR (µg/cm2)(c)	No. of workers Monitored(d)	Mean dermal exposure per harvester (mg/8 hour workday)	Transfer factor for harvesters (cm2/hour)(e)	Total foliage contacted by all harvesters in crew (cm2/hour)(f)
Phosalone	Peaches						
1977 (2,3)	Stanislaus County	3-5	2.89	six (4)	111	4,810	28,900
Azinphos-methyl	Peaches						
1976 (2,3)	Stanislaus County	22-24	0.20	six (4)	12.3	7,689	46,100
Propargite	Peaches						
1988 (4)	Fresno County	34	0.59	ten	5.17	1,095	11,000
Propargite	Peaches						
1988 (4)	Fresno County	39	0.54	ten	5.55	1,285	12,900
Propargite	Peaches						
1988 (4)	Fresno County	45	0.48	ten	3.65	950	9,500

Weighted Mean Transfer Factor for all Data = Sum of Total Foliage Contacted by All Harvesters in Each Study divided by the Total Number of Workers Monitored in All Studies.
= 4023 ug^2/hour

(a) Sources of data.
(1) Spencer et al., 1993.
(2) Popendorf et al., 1979.
(3) Popendorf and Leffingwell, 1982.
(4) Rech, 1989.

(b) The number of days after the pesticide application when the dislodgeable foliar residue samples were taken.

(c) DFR = Dislodgeable Foliar Residues. The DFR reported in Popendorf and Leffingwell (1982) were divided by 2 to calculate the DFR for both sides of the leaf.

(d) The number of harvesters monitored for dermal exposure with patch dosimetry for a 4-8 hour exposure period per workday.
(4) Each worker (ten total) only wore two patches and the patches were pooled at the end of workday to approximate the total dermal exposure for two workers. Therefore, each harvest day was considered two workdays.

(e) Formula for calculating Transfer Factor:
Mg of dermal exposure per workday X 1,000 ug/mg divided by observed DFR X 8 hr/day.

(f) Calculated by multiplying the number of workers monitored by the transfer factor.

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